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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,357	02/13/2002	Fanie Retief Van Heerden	013306-5001-02US	5958

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EXAMINER	
KHARE, DEVESH	
ART UNIT	**PAPER NUMBER**
1623	

DATE MAILED: 11/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicati n No.	Applicant(s)	
	10/073,357	VAN HEERDEN ET AL.	
	Examiner	Art Unit	
	Devesh Khare	1623	

-- The MAILING DATE of this communication appears n the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 August 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,14-21 and 23-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,14-21 and 23-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *8/11/03* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Applicant's Amendment and response filed on 8/14/03 is acknowledged.

Claims 13 and 22 have been cancelled. New claims 25-27 have been added. The corrected drawings have been accepted. The terminal disclaimer filed on 8/11/03 (paper # 12) has been entered. Currently, claims 1-12, 14-21, and 23-27 are under examination.

Provisional "Non-Statutory" Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

> Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 9-12,14,15,18-21,23 and 24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No.6,376,657 ('657), of record.

Although the conflicting claims are not identical, they are not patentably distinct from each other because '657 claims an extract obtained from a plant of the genus *Trichocaulon* or the genus *Hoodia* and a method of combating obesity in a human or animal by administering an obesity combating amount of an extract obtained from a

plant of the genus *Trichocaulon* or the genus *Hoodia* according to instant claims 9-12,14,15,18-21,23 and 24.

The issued patent '657 differ from the present application in that it does not claim a method of suppressing appetite in a human or animal by administering a suitable dosage of an extract obtained from a plant of the genus *Trichocaulon* or the genus *Hoodia*.

Claims 15 and 24 are directed to an invention not patentably distinct from claims 122 and 130 of commonly assigned Application No. 10/170,750. Specifically, a method of suppressing appetite in a human or animal.

Claims 15 and 24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 122 and 130 of copending Application No. 10/170,750 ('750). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed toward a method of suppressing appetite in a human or animal by administering a suitable dosage of an extract obtained from a plant of the genus *Trichocaulon* or the genus *Hoodia*. '750 differ from the present application in that in a method of suppressing appetite in a human or animal by using the extract obtained from a plant of the genus *Trichocaulon* or the genus *Hoodia,* the said extract is admixed with an excipient, diluent or carrier.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

35 U.S.C. 103(a) rejection

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> *(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.*

Claims 1-8,16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wada et al. (Chem. Pharm. Sci. Bull. (1982), 30(10), 3500-4) in view of Brunyns (Bot. Jahrb. Syst. Vol.115, no.2, pages 145-270, 1993), of record.

Claims 1-8, 16 and 17, are drawn to a process for preparing an extract of a plant of the genus *Trichocaulon* or of the genus *Hoodia*. The process includes the steps of treating plant material with a solvent to extract a fraction having appetite suppressant activity, separating the extraction solution from the rest of the plant material, removing the solvent from the extraction solution and recovering the extract.

Additional claim limitations include the use of methylene chloride, water, methanol, hexane, ethyl acetate or mixtures thereof in the solvent extraction step, separating sap from the solid plant material, forming a free-flowing powder from the extract and chromatographic separation of the active agent in the extracted material on a column.

Wada et al. teach a method of extraction of a plant of the genus *Asclepiadaceae* (see abstract). Wada et al. disclose the steps of treating plant material with chlororform and methanol, separating the extraction solution from the rest of the plant material, further extraction of methanol soluble portion with hexane and hexane-benzene solvent mixture and removing the solvent from the extraction solution and recovering the extract (see chart 1 on page 3500 and Experimental on page 3503). Furthermore, the use of

chromatographic separation of active agent in the extracted material is disclosed on page 3503 under the Experimental.

While the Wada et al.'s process for preparing an extract of a plant and separating active agent from the extract is closely analogous to applicants, Wada et al. differ from applicant's process for preparing an extract of a plant, particularly extraction of a plant of the genus *Trichocaulon* or of the genus *Hoodia,* separating sap from the solid plant material and forming a free-flowing powder from the extract. Use of a known member of a class of materials in a process is not patentable if other members of the class were known to be useful for that purpose, even though results are better than expected.

Bruyns teaches various species of a plant of the genus *Trichocaulon* and of the genus *Hoodia* (see abstract). Bruyns discloses the medical use of the plants of genus *Trichocaulon* and *Hoodia,* particularly as appetite suppressant and thirst quenching agents (see page 175, under 'uses' through page 176, first paragraph). Bruyns does not disclose a process for preparing an extract of these plants.

Therefore, one of ordinary skill in the art would have found the applicants claimed process for preparing an extract of a plant of the genus *Trichocaulon* or of the genus *Hoodia*, having appetite suppressant activity to have been obvious at the time the invention was made having the above cited references before him. Since Wada et al. teach a process for preparing an extract of a plant of the genus *Asclepiadaceae* and Bruyns discloses the medical use of the plants of genus *Trichocaulon* and *Hoodia,* particularly as appetite suppressant, one skilled in the art would have a reasonable expectation for success in combining the teachings of these references to accomplish a

process for preparing an extract of a plant of the genus *Trichocaulon* or of the genus *Hoodia*, having appetite suppressant activity. The motivation for doing so is provided by Bruyns, which discloses the hunger suppressant activity of the preserve of the plants of genus *Trichocaulon* and *Hoodia* (see lines 1-4 on page 176).

Rejection Maintained

Rejections of claims 9-12,14,15,18-21,23 and 24 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No.6,376,657 ('657) and claims 1-8,16 and 17 under 35 U.S.C. 103(a) as being unpatentable over Wada et al. (Chem. Pharm. Sci. Bull. (1982), 30(10), 3500-4) in view of Brunyns (Bot. Jahrb. Syst. Vol.115, no.2, pages 145-270, 1993), are maintained. New claims 25 and 26 are also rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No.6,376,657 ('657). New claim 27 is also rejected under 35 U.S.C. 103(a) as being unpatentable over Wada et al. (Chem. Pharm. Sci. Bull. (1982), 30(10), 3500-4) in view of Brunyns (Bot. Jahrb. Syst. Vol.115, no.2, pages 145-270, 1993), as already applied to claims 1-8, 16 and 17.

In claims 25 and 26, applicants claim a medicament comprising an extract of claim 9 and claim 19. Claims 25 and 26 are not patentably distinct over claims 1-10 of U.S. Patent No.6,376,657 ('657), because '657 claims an extract obtained from a plant of the genus *Trichocaulon* or the genus *Hoodia*.

In claim 27, applicants claim a process for preparing a purified extract of a plant of the genus *Trichocaulon* or of the genus *Hoodia*. Since claim 27 includes the process for

preparing an extract of a plant of the genus *Trichocaulon* or of the genus *Hoodia*, claim 27 is obvious within the prior art already set forth in the rejections of claims 1-8, 16 and 17.

Response to Arguments

Applicant's arguments filed on August 14,2003 traversing the rejection of claims 1-8,16 and 17 under 35 U.S.C 103(a) have been fully considered but they are not persuasive. Applicants claim that "Bruyns clearly does not identify any potential appetite suppressant properties associated with the disclosed plant strips, a person skilled in the art would not be motivated to combine Bruyns with Wada to achieve Applicants' invention". Regarding Wada reference, Wada teaches a process for preparing an extract of a plant of the genus *Asclepiadaceae* (page 3500, Chart 1). It is noted that Wada's process for preparing an extract of a plant is closely analogous to applicants. Regarding Bruyns reference, applicants are referred to page 176, lines 1-2, wherein the hunger quench properties of the stems of *Trichocaulon*, is disclosed. Bruyns reference also discloses the medicinal use of the *Hoodia* plant on page 175, lines1-2, under uses. One skilled in the art would have a reasonable expectation for success in combining the teachings of these references to accomplish a process for preparing an extract of a plant of the genus *Trichocaulon*, having appetite suppressant activity. Applicant has not demonstrated any criticality or unexpected result, which stems from the process for preparing an extract of a plant of the genus *Trichocaulon* or genus *Hoodia*.

2. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Devesh Khare whose telephone number is (703)605-1199. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, Supervisory Patent Examiner, Art Unit 1623 can be reached at 703-308-4624. The official fax phone numbers for the organization where this application or proceeding is assigned is (703) 308-4556 or 308-4242.
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Devesh Khare, Ph.D.,JD(3Y).
Art Unit 1623
October 31,2003

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
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